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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,467	11/28/2003	Philippe Du Mesnil	P63187US2	7970

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EXAMINER	
CHONG, YONG SOO	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
09/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,467	DU MESNIL ET AL.	
	Examiner	Art Unit	
	YONG S. CHONG	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-21* is/are rejected.

7)☒ Claim(s) *15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/234,381.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/19/08 has been entered.

Claim(s) 1-11 have been cancelled. Claim(s) 21 has been added. Claim(s) 12-21 are pending. Claim(s) 12 has been amended. Claim(s) 12-21 are examined herein.

Applicant's amendments have rendered the 103(a) rejection of the last Office Action moot, therefore hereby withdrawn. The following new rejection will now apply.

Claim Objections

Claim 15 is objected to because of the following informalities: There is an extra slash mark after "0.001 mg/kg/" that is unneeded. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of US Patent 6,455,514 B2 and claims 1-7 of US Patent 6,696,429 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are an obvious variation since both disclose a method of treating lameness in horses by administering bisphosphonic acid derivatives of the same scope.

Claims 12-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-20 of copending Application No. 11/406,296. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are an obvious variation since both disclose a method of treating lameness in horses by administering bisphosphonic acid derivatives of the same scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 12-21 are rejected under 35 U.S.C. 103(a) as being obvious over Barbier et al. (US Patent 5,488,041) in view of Huber et al. (US Patent 3,637,641).

The instant claims are directed to a method of treating lameness caused by osteoarthrosis comprising administering to a non-human animal not suffering from fractures an effective amount of a bisphosphonic acid derivative selected from claim 12.

Barbier et al. teach promoting bone repair in human and veterinary medicine by administering a therapeutically effective amount of bisphosphonic acid derivative of formula I (abstract). A preferred compound is 4-chlorophenyl thiomethylenebisphosphonic acid (col. 2, line 9). Various salt forms are disclosed including tiludronic acid. The biological effect of bisphosphonic acid derivatives is to

inhibit bone resorption by reducing the activity of the osteoclasts (col. 2, lines 25-30). Several bisphosphonic acid derivatives are currently being developed for humans for use in the treatment of bone diseases such as Paget's disease and osteoporosis, which are characterized by an osteoclastic stimulation (col. 2, lines 44-49). The physiological process of bone repair is defined as the successive appearance of different cicatricial tissues in the following order: cartilage, primary bone, and lamellar bone. Each of these is only formed after the destruction of the previous one. Such a change is therefore due to a resorption, which is ensured by macrophagic cells: the chondroclasts for cartilage resorption and the osteoclasts for bone resorption (col. 1, lines 8-15). Barbier et al. teach that these bisphosphonic acid derivatives can be administered orally, parentally, intravenous, transdermally, or by an implant (col. 3, lines 19-21). The daily dosage unit can comprise from 0.001 mg to 1.2 g of bisphosphonic acid derivative (col. 3, lines 40-42). For an average horse weighing 1000 pounds, this equates to a weight of 453 kg, which further equates to 0.453 mg of active agent at the rate of 0.001 mg/kg as specified in claim 15.

Barbier et al. teach as disclosed above, however, fail to specifically disclose treating lameness in horses.

Huber et al. teach an abnormal bone condition called bony exostosis is common in animals, especially horses. Bony exostosis involves the first, second, and third phalanges, as well as sesamoid bone, cannon bone, and carpal joints. In its various clinical manifestations, it is known as asteoarthritis (or osteoarthritis) of the carpal joints, splits, osselets, sesamoiditis, ringbone, sidebone, and navicular disease (col. 2, lines

10-18). Bony exostosis may be the result of several factors, including hereditary predisposition, faulty nutrition, and conformation, improper shoeing, and traumatism. Initial symptoms include lameness and difficulty in locomotion (limping) followed by enlargements around the effected joint. Some of the bony structural abnormalities are areas of osteoclastic activity (col. 2, lines 35-44).

It is noted that the limitation "caused by osteoarthrosis" in claim 12 is given little patentable weight since the disorder, lameness, is still clinically the same no matter what the etiology or origin of the disorder is.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to have administered a bisphosphonic acid derivative, for example 4-chlorophenyl thiomethylenebisphosphonic acid, as taught by Barbier et al. to treat lameness in a horse as taught by Huber et al.

A person of ordinary skill in the art would have been motivated to administer a bisphosphonic acid derivative, for example 4-chlorophenyl thiomethylenebisphosphonic acid, as taught by Barbier et al. to treat lameness in a horse as taught by Huber et al. because: (1) Barbier et al. teach broadly that bisphosphonic acid derivatives are useful for treating bone disorders; and (2) Huber et al. teach that bony exostosis is a common bone disorder in horses characterized by lameness and difficulty in locomotion or limping. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating lameness in horses by administering a bisphosphonic acid derivative, such as 4-chlorophenyl thiomethylenebisphosphonic acid.

Response to Arguments

Applicant's arguments as well as the Thibaud Declaration under 37 CFR 1.132 filed 5/19/08 are considered moot in light of the new grounds of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong S Chong/
Examiner, Art Unit 1617

YSC